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| 09/763,824 | 02/27/2001 | David J Squirrell | 1498-119 | 3738 |

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EXAMINER

STEADMAN, DAVID J

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1656

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,824

Applicant(s)

SQUIRRELL ET AL.

Examiner

David J. Steadman

Art Unit

1652 / 656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-66 is/are pending in the application.
4a) Of the above claim(s) 36, 39-50 and 63 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 31-35, 37, 38, 51-62 and 64-66 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 27 February 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/15/05
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1]** The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
- [2]** Claims 31-66 are pending in the application.
- [3]** Applicants' amendment to the claims, filed 4/15/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [4]** Applicants' amendment to the specification, filed 4/15/2005, is acknowledged.
- [5]** Applicants' amendment to the drawings, filed 4/15/2005, is acknowledged.
- [6]** Receipt of an information disclosure statement (IDS), filed 4/15/2005, is acknowledged.
- [7]** Receipt of a petition, filed on 4/15/2005, to withdraw the restriction requirement is acknowledged. In view of the decision on petition as set forth in the Office communication mailed 8/26/2005, this Office action is non-final.
- [8]** Applicants' arguments filed on 4/15/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [9]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Lack of Unity

[10] Claims 36, 39-50, and 63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/1/2004.

[11] In view of the decision on petition, claim 56 is now rejoined with the claims of elected Group 1(a). Thus, claims 31-35, 37-38, 51-62, and 64-66 are being examined on the merits only to the extent the claims read on the elected subject matter.

Information Disclosure Statement

[12] The reference cited in the information disclosure statement (IDS), filed on 4/15/2005, has been considered by the examiner and a copy of Form PTO-1449 is attached to the instant Office action.

Specification/Informalities

[13] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: --Thermostable *Photinus pyralis* Luciferase Mutant--. While applicants argue the title suggested by the examiner is not appropriate, this is not found persuasive in view of the decision on petition.

[14] When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be

included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. MPEP § 2422.02. See particularly Figure 5. While applicants argue the objection is unfounded in view of the amendment to the specification filed on 8/19/2002, this is not found persuasive because no amendment to Figure 5 or the description thereof has been made in the specification amendment filed on 8/19/2002. It appears that applicants are referring to an amendment to the description of Figure 8, which was added by the amendment filed on 8/19/2002. However, it is noted that there is no Figure 8 in the drawing figures. This amendment should be corrected to indicate Figure 5 and not Figure 8. Even if the amendment was directed to the description of Figure 5, it is noted that it is not clear as to which sequence disclosed in Figure 5 has the corresponding sequence identifier. It is suggested that applicants amend Figure 5 to show the corresponding sequence identifier listed next to the disclosed sequence. Appropriate correction is required.

Claim Objections

[15] Claims 31, 34-35, 37-38, and 61-62 are objected to as reciting non-elected subject matter. Applicants request the objection be held in abeyance. In view of the decision on petition, it is suggested that applicants amend the claims so that they no longer recite non-elected subject matter.

[16] Claim 34 is objected to as the claim does not end with a period.

[17] Claim 62 is objected to as being grammatically incorrect in the recitation of “the sequence of an enzyme a luciferase.” It is suggested that the phrase “the sequence of an enzyme a luciferase” be amended to read “the sequence of a luciferase.”

Claim Rejections - 35 USC § 112, Second Paragraph

[18] The rejection of claims 31-35, 37-38, 51-62, and 64-66 as being indefinite in the recitation of “60% similarity to luciferase from *Photinus pyralis*,” “the amino acid corresponding to residue 214 in *Photinus pyralis*,” “the sequence of a wild-type luciferase,” “the sequence of luciferase of *Photinus pyralis*,” and “residue 214 in *Photinus pyralis* luciferase” is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue “[t]he specification clearly describes that correspondence of particular amino acids should be determined by reference to Ye et al.” Applicants argue the metes and bounds of the claimed invention “will be appreciated by one of ordinary skill” as the sequences and corresponding amino acid positions are allegedly taught by the specification.

Applicants' argument is not found persuasive. There is no dispute that a sequence of a *Photinus pyralis* luciferase polypeptide was known in the art at the time of the invention as evidenced by Ye et al. However, the examiner can find no express definition in the specification that limits the intended sequence of a *Photinus pyralis* luciferase polypeptide to that disclosed by Ye et al. As such, it is unclear as to the scope of claimed recombinant proteins and encoding nucleic acids. Even if such an express

definition were present, it is noted that the intended *Photinus pyralis* luciferase amino acid sequence is "essential material" because it is necessary to describe the claimed invention and because it is "essential material," it may not be incorporated by reference to a non-patent document. Thus, the intended *Photinus pyralis* luciferase amino acid sequence should be disclosed in the specification. Applicants are advised that "[m]ere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph." See MPEP 608.01(p).

[19] Claims 35, 57, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claim 35 is incomplete as the claim appears to prematurely terminate. It is suggested that applicants clarify the claim.

[b] Claim 57 is indefinite as the claim depends from a canceled claim. In the interest of advancing prosecution, the examiner has interpreted the claim as being dependent upon claim 31.

[c] Claim 57 recites the limitation "the improvement." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112, First Paragraph

[20] The written description rejection of claims 31-35, 37-38, 51-62, and 64-66 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the claimed genus of polypeptides and nucleic acids is described by disclosure of relevant identifying characteristics, by functional characteristics coupled with a known or disclosed correlation between function and structure and by the disclosed examples. Regarding the disclosed examples, applicants point to Example 7, which discloses the construction of position 214 mutants of the *Photinus pyralis* luciferase having the sequence as set forth in Ye et al. Applicants urge the examiner to "appreciate that the specification provides more than one example" of a *Photinus pyralis* luciferase with mutation at position 214, *i.e.*, *Photinus pyralis* luciferase with mutation at position 214 and optionally mutation at position(s) 215, 232, and/or 354.

Applicants' argument is not found persuasive. Initially, as noted above, the specification fails to define what is intended as being the sequence of a *Photinus pyralis* luciferase and it follows that it is unclear as to those polypeptides that share at least 60 identity thereto. The examiner acknowledges that all members of the genus have a defined function, *i.e.*, the polypeptides have luciferase activity and the nucleic acids encode polypeptides that have luciferase activity. However, even assuming *arguendo* the intended sequence of *Photinus pyralis* luciferase is that disclosed by Ye et al., at 60% identity, this would allow up to 220 amino acid substitutions (40% x 550 amino acids). As such, the genus encompasses species that are widely variant with respect to

their structures. In this case, the genus is not adequately described as the disclosed species, *i.e.*, *Photinus pyralis* luciferase with mutation at position 214 and optionally mutation at position(s) 215, 232, and/or 354, fail to represent the structural variation within the genus. Given the lack of description of a representative number of recombinant proteins, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[21] The scope of enablement rejection of claims 31-35, 37-38, 51-62, and 64-66 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the examiner's comments regarding absolute predictability are not an accurate reflection of the approach that would be taken by a skilled artisan in making the claimed invention. Instead of making all mutants as encompassed by the claims, applicants argue a skilled artisan would produce a single sequence within the scope of the claims and make one or two mutations to that sequence and if these mutants are found to have the desired effect(s), additional mutants can be made. Applicants argue such mutations are within the scope of reasonable experimentation.

Applicants' argument is not found persuasive. Regarding predictability in the art, MPEP 2164.03 states, "[i]f one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily

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anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art." Contrary to applicants' assertion, the examiner has not required "absolute predictability." Instead, the examiner has set forth a line reasoning that the functional effects as a result of altering a polypeptide sequence are highly unpredictable. The examiner's position is supported by the prior art references of Branden et al. and Witkoski et al. (cited in the previous Office action). It should be noted that the high level of unpredictability in the art is undisputed by applicants.

Regardless of the approach taken to make the claimed invention, the specification should enable the *full scope* of the claimed invention, not just a relatively few species encompassed by a much larger claim scope. As noted above, even assuming *arguendo* the intended sequence of *Photinus pyralis* luciferase is that disclosed by Ye et al., at 60% identity, this would allow up to 220 amino acid substitutions (40% x 550 amino acids). Alteration of up to 220 amino acids of a polypeptide to isolate those that have a desired activity was not routinely practiced at the time of the invention.

Applicants argue that because luciferases are highly conserved, it is reasonable to believe that a mutation that is found to have a desired effect in one luciferase would have the desired effect in other luciferases.

Applicants' argument is not found persuasive. While one of skill in the art may be able to predict that a *single* mutation in *Photinus pyralis* luciferase that has a desired effect will have a similar effect in luciferases from other sources when mutated at the

corresponding position, there is no way to predict the effect(s) of up to 220 simultaneous amino acid substitutions in other luciferases.

Applicants argue the specification discloses several working examples of the claimed invention, pointing to Examples 2, 3, 7, and 8 of the specification. In view of these working examples, applicants argue the specification provides sufficient direction to make the full scope of the claimed invention.

Applicants' argument is not found persuasive. It is noted that the mutants disclosed in Examples 2 and 8 do not appear to be encompassed by the claims. Regarding Examples 3 and 7, Example 3 appears to disclose a *Photinus pyralis* luciferase having mutation at positions 214, 232, and 354 and Example 7 appears to disclose a *Photinus pyralis* luciferase having mutation at position 214. As previously noted, the specification is enabling for a *Photinus pyralis* luciferase having a substitution of threonine at position 214 and optionally mutations at positions 215, 232, and/or 354 and a nucleic acid encoding therefor. However, the working examples of mutant *Photinus pyralis* luciferases of Examples 3 and 7 fail to provide the necessary guidance for making the full scope of claimed polypeptides and nucleic acids, particularly in view of the broad scope of the claims, the high level of unpredictability, and the amount of experimentation required.

Claim Rejections - 35 USC § 102

[22] Claims 31-32, 34-35, 37, 51-52, 60-62, and 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Database EMBL Accession Number D25415 as

evidenced by Wood et al. (US Patent Application Publication 2003/0068801). The claims are drawn to a recombinant luciferase protein having at least 60% identity to *Photinus pyralis* luciferase with the amino acid at position 214 of *Photinus pyralis* luciferase replaced with another amino acid and wherein the luciferase protein has increased thermostability, a nucleic acid encoding the same, and vectors and host cells comprising said nucleic acid.

Database EMBL Accession Number D25415 teaches a nucleic acid sequence encoding a *P. pennsylvanica* luciferase polypeptide and the amino acid sequence of the encoded polypeptide. The encoded polypeptide has an asparagine at the position corresponding to position 214 of *P. pyralis* luciferase (see Appendix A of the Office action mailed 12/15/2004). This anticipates claims 31-32, 34-35, 37, 51-52, 60-62, and 64-65 as written.

Wood et al. is cited in accordance with MPEP 2131.01 as an evidentiary reference showing that *P. pennsylvanica* luciferase has a greater thermostability than *P. pyralis* luciferase (see ¶ [0011]).

RESPONSE TO ARGUMENT: Applicants argue the reference teaches a wild-type sequence and therefore does not anticipate the claimed invention.

Applicants' argument is not found persuasive. At the time of the invention, a skilled artisan would recognize that one could alter the sequence of *Photinus pyralis* luciferase such that it is identical to the sequence of the *Photinus pennsylvanica* luciferase of Database EMBL Accession Number D25415. One comparing such a mutant *Photinus pyralis* luciferase sequence with the *Photinus pennsylvanica* luciferase

of Database EMBL Accession Number D25415 would not be able to distinguish the two sequences because they would be identical. While applicants may see the polypeptide of Database EMBL Accession Number D25415 as a "wild-type" *Photinus pennsylvanica* sequence, the examiner views the same sequence as a "mutant" *Photinus pyralis* luciferase polypeptide. Thus, although the polypeptide disclosed by Database EMBL Accession Number D25415 is denoted as a *Photinus pennsylvanica* luciferase, it is equally a mutated form of *Photinus pyralis* luciferase. As the sequence meets all the limitations of the claims, *i.e.*, it has luciferase activity, it has at least 60% identity to a *Photinus pyralis* luciferase polypeptide, and is considered to be a "mutated" *Photinus pyralis* luciferase polypeptide, the reference of Database EMBL Accession Number D25415 anticipates claims 31-32, 34-35, 37, 51-52, 60-62, and 64-65 as written.

[23] Claims 31-32, 34-35, 37, 51-54, 57-62, and 64-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Wood et al. (US Patent Application Publication 2003/0068801). Claims 31-32, 34-35, 37, 51-52, 60-62, and 64-65 are drawn to the invention as stated above. Claims 53-54, 57-59, and 66 are drawn to a method of using the recombinant luciferase protein in a bioluminescence assay, a kit comprising the claimed protein, a vector comprising the claimed nucleic acid, and a host cell comprising said vector.

Wood et al. teaches thermostable *P. pennsylvanica* luciferase polypeptides of SEQ ID NO:27-28, 30, and 32-33 (for a representative alignment with SEQ ID NO:32, see Appendix B of the Office action mailed 12/15/2004) and corresponding encoding nucleic acid, a vector comprising said nucleic acid, a host cell, including a prokaryotic

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host cell, comprising said vector (see, e.g., paragraph [0009]), a method of using their protein in a luminescence assay for detecting ATP and luciferin in a sample using their luciferase (see, e.g., paragraph [0073]), and teach an embodiment of their invention as being a kit comprising their protein (see, e.g., paragraph [0009]). Wood et al. teaches *P. pennsylvanica* luciferase has greater thermostability than *Photinus pyralis* luciferase, thus it follows that the mutants of Wood et al. have greater thermostability as compared to *Photinus pyralis* luciferase. This anticipates claims 31-32, 34-35, 37, 51-54, 57-62, and 64-66 as written.

RESPONSE TO ARGUMENT: Applicants argue the reference teaches a wild-type sequence and therefore does not anticipate the claimed invention.

Applicants' argument is not found persuasive. It is noted that the sequences of Wood et al. are not "wild-type" *Photinus pennsylvanica* luciferase sequences, but are disclosed as being *Photinus pennsylvanica* luciferase mutants that have increased thermostability. At the time of the invention, a skilled artisan would recognize that one could alter the sequence of *Photinus pyralis* luciferase such that it is identical to any one of the sequences of the *Photinus pennsylvanica* luciferases of Wood et al. One comparing such a mutant *Photinus pyralis* luciferase sequence with the *Photinus pennsylvanica* luciferase of Wood et al. would not be able to distinguish the two sequences because they have identical sequences. While applicants may see the polypeptides of Wood et al. as *Photinus pennsylvanica* sequence, the examiner views the same sequence as a "mutant" *Photinus pyralis* luciferase polypeptide. Thus, although the polypeptides disclosed by Wood et al. are denoted as *Photinus*

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pennsylvanica luciferases, they are also mutated forms of a *Photinus pyralis* luciferase.

As the sequences of Wood et al. meet all the limitations of the claims, *i.e.*, they have luciferase activity, they have at least 60% identity to a *Photinus pyralis* luciferase polypeptide, and are considered to be "mutated" *Photinus pyralis* luciferase polypeptides, the reference of Wood et al. anticipates claims 31-32, 34-35, 37, 51-54, 57-62, and 64-66 as written.

Claim Rejections - 35 USC § 103

[24] Claim(s) 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Firoozabady et al. (US Patent 5,480,789) in view of Wood et al. Claim 55 is drawn to a plant cell transformed with the vector of claim 52; claim 56 is drawn to a plant comprising the plant cell of claim 55.

Firoozabady et al. teaches transformation of rose plant cells with a vector comprising a nucleic acid encoding luciferase (claim 13) and the use of the resulting transformed rose plant cell for generation of a whole rose plant (claim 2).

Wood et al. discloses the teachings as described above.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Firoozabady et al. and Wood et al. to practice the method of Firoozabady et al. using a vector comprising the nucleic acid of Wood et al. One would have been motivated to transform a rose plant cell using a vector comprising the nucleic acid of Wood et al. in order to produce a rose plant cell expressing a *thermostable* luciferase. One would have a reasonable expectation of success for

practicing the method of Firoozabady et al. using a vector comprising the nucleic acid of Wood et al. because of the results of Firoozabady et al. and Wood et al. Therefore, claims 55-56, drawn to a plant cell and a plant as described above would have been obvious to one of ordinary skill in the art at the time of the invention.

RESPONSE TO ARGUMENT: Addressing the previous rejection under 35 U.S.C. 103(a), applicants argue the claims are patentable over the cited prior art.

Applicants' argument is not found persuasive. Initially, it is noted that the previous rejection under 35 U.S.C. 103(a) has been withdrawn, not in view of applicants' arguments, but instead in view of rejoinder of claim 56 with the claims of the elected invention. The reference of Gustafson et al. does not expressly teach a plant generated from their transformed plant cell, thus the examiner has cited the reference of Firoozabady et al. in combination with the reference of Wood et al. as teaching the limitations of claims 55 and 56. For the reasons stated above, the examiner holds the position that the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

Double Patenting Rejection(s)

[25] The provisional obviousness-type double patenting rejection of claims 1-5, 7-8, and 21-23 as being unpatentable over claims 1-4, 6-10, 14, 17-19 and 6-23 of co-pending Application No. 10/111,723 is maintained for the reasons of record.

Applicants request the provisional rejection be held in abeyance. Applicants' request is acknowledged.

Conclusion

[26] Status of the claims:

Claims 31-66 are pending.

Claims 36, 39-50, and 63 are withdrawn from consideration.

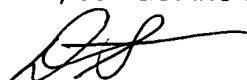
Claims 31-35, 37-38, 51-62, and 64-66 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 7:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656